

Message

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**From:** Jinot, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D0EDF66A00054AFE84F4AB5C5119562F-JINOT, JENNIFER]  
**Sent:** 11/13/2014 9:02:06 PM  
**To:** Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]  
**Subject:** RE: CAAC EtO - Request for additional information

## Deliberative Process / Ex. 5

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**From:** Bussard, David  
**Sent:** Thursday, November 13, 2014 3:53 PM  
**To:** Jinot, Jennifer; Jones, Samantha; Gwinn, Maureen  
**Cc:** Perovich, Gina; Cogliano, Vincent; Flowers, Lynn; Vandenberg, John; Walsh, Debra; Subramaniam, Ravi  
**Subject:** RE: CAAC EtO - Request for additional information

## Deliberative Process / Ex. 5

David A Bussard

Director, Washington Division  
National Center for Environmental Assessment  
ORD, USEPA

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**From:** Jinot, Jennifer  
**Sent:** Thursday, November 13, 2014 2:36 PM  
**To:** Jones, Samantha; Bussard, David; Gwinn, Maureen  
**Cc:** Perovich, Gina; Cogliano, Vincent; Flowers, Lynn; Vandenberg, John; Walsh, Debra; Subramaniam, Ravi  
**Subject:** RE: CAAC EtO - Request for additional information

## Deliberative Process / Ex. 5

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**From:** Jones, Samantha  
**Sent:** Monday, November 03, 2014 5:25 PM  
**To:** Bussard, David; Gwinn, Maureen; Ross, Mary; Jinot, Jennifer  
**Cc:** Perovich, Gina; Cogliano, Vincent; Flowers, Lynn; Vandenberg, John; Walsh, Debra  
**Subject:** FW: CAAC EtO - Request for additional information

Deliberative Process / Ex. 5

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**From:** Yeow, Aaron  
**Sent:** Monday, November 03, 2014 5:09 PM  
**To:** Perovich, Gina; Jones, Samantha; Cogliano, Vincent  
**Cc:** Brennan, Thomas; Shallal, Suhair  
**Subject:** CAAC EtO - Request for additional information

Gina, Sam,

Dr. Lianne Sheppard has requested the following additional information to aid in her responding to the charge questions. The best way to provide this information is to send it to me in a memo, which will then be shared with the augmented CAAC and with the public on our website.

Ethylene Oxide additional information requested:

- Please provide the data indicated in footnote 15 on page 4-3.
- Provide a "Table 1" for each of the analysis datasets giving summary statistics for demographic variables, key covariates, potential confounders, duration of observation, duration of employment, year of first employment, etc. Separate columns for cases and noncases.
- Summarize the exposure distribution for the analysis datasets (e.g. nested case-control). Give descriptive statistics and consider showing as two histograms, one for cases and one for all controls selected into all risk sets.
- Provide the SEs of the linear combination of coefficients for the spline models after the knot
  - P. D-58: Need the SE of spl1+spl2
  - Table 4-3: add in the slope after the knot with its SE
- Add to the tables (Table 4-2, 4-7, others) the RR estimates and their 95% CIs at the exposure means. Also calculate and present for the exposure medians. Make sure to include the category means and medians in the footnotes, not just the ranges.
- Add additional modeling results in Table 4-3 to facilitate comparisons. In particular, the log-cumulative exposure results should be included. Also the estimated slope after the knot and its SE. (These are obtained as a linear combination of B1 and B2).
- Clarify calculations, and information used in the calculations, most likely in an appendix:
  - Go through all the details of one set of unit risk estimate calculations. Provide the rationale for each adjustment factor, etc. Show an approximate "back of the envelope" estimate using overall (i.e. age-adjusted rather than age-specific) estimates of background rates.
  - Please connect the extra risk formula (4-2) on p 4-7 with the unit risk calculations. Please define the terms more clearly and present in the context of examples.
  - Provide a table of sample ppm-day to ppm conversions for use in the EC01 calculations. Give conversion values at the knots and also for some of the results. (A few of these conversions are in table footnotes, e.g. Table 4-5.)
  - Please provide a table of overall estimates of background rates (i.e. crude, age-adjusted) for all cancer outcomes considered in this document.

-Aaron

Aaron Yeow, M.P.H.  
Designated Federal Officer  
U.S. Environmental Protection Agency  
Science Advisory Board  
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